AS/NZS ISO 9001:2008

Quality Management Systems (QMS)

Self-Assessment Checklist

This document restates the requirements of AS/NZS ISO 9001:2008 for Quality Management Systems (QMS) and has been developed to assist BSI and its' clients in the assessment of quality management systems for compliance with ISO 9001:2008.

This checklist presents the requirements of AS/NZS ISO 9001:2008 as questions and can be used as an effective tool for implementing the quality management system and for self-assessment of the system.

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SCOPE OF CERTIFICATION What is the scope of the quality management system to be included in the certification? What activities and processes are not being included in the Scope of the Certification? Include justification for exclusion. ***NOTE**: Only activities or processes relating to Section 7 of ISO 9001:2008 can be excluded from the Scope of Certification.* **1.2 Application** The requirements of the ISO9001:2008 standard are generic and are applicable to all organizations irrespective of type, size and product provided. Where the requirement of the standard cannot be applied due to the nature of the product, has the organization claimed a documented exclusion? Is the claimed exclusion limited within the requirements of clause 7 of the standard, and does the exclusion affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements?	

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4. QUALITY MANAGEMENT SYSTEM **4.1 General requirements** Has the organization established, documented, implemented and maintained a quality management system and continually improved its effectiveness in accordance with the requirements of this International Standard? Has the organization: a) identified the processes needed for the quality management system and their application throughout the organization; b) determined the sequence and interaction of these processes; c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes; e) monitored, measured and analysed these processes, and f) implemented actions necessary to achieve planned results and continual improvement of these processes? Are these processes managed by the organization in accordance with the requirements of this International Standard?	

NOTE 1. *Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.* Where processes which affect product conformity to requirements have been outsourced, has the type and extent of control of such processes been identified in the quality management system? **NOTE 2**. *An outsourced process is identified as one needed for the organization's quality management system but chosen to be performed by a party external to the organization.* **NOTE 3.** *Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:* *a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,* *b) the degree to which the control for the process is shared,* *c) the capability of achieving the necessary control through the application of 7.4.*	

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4.2 Documentation requirements **4.2.1 General** Does the quality management system documentation include: a) documented statements of quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International standard; d) documents, including records needed by the organization to ensure the effective planning, operation and control of it's processes. **Note 1.** *Where the term "documented procedure" appears, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.* **Note 2.** *The extent of the quality management system documentation can differ from one organization to another due to:* *a) the size of the organization and type of activities;* *b) the complexity of processes and their interactions, and* *c) the competence of personnel* **Note 3.** *The documentation can be in any form or type of medium.*	

4.2.2 Quality manual Has the organization established and maintained a quality manual that includes: a) the scope of the quality management system, including details and justification for any exclusions b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system?	
4.2.3 Control of documents Are documents required by the quality management system controlled? Has a documented procedure defining the controls needed been established: d) to approve documents for adequacy prior to issue; e) to review and update as necessary and re-approve documents; f) to ensure that changes and the current revision status of documents are identified g) to ensure that relevant versions of applicable documents are available at points of use; h) to ensure that documents remain legible and readily identifiable; i) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality system are identified and their distribution controlled; and j) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	

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4.2.4 Control of records Are the records established to provide evidence of conformity to requirements and of the effective operation of the quality management system controlled? Has a documented procedure been established that defines the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records? Are records legible, readily identifiable, and retrievable?	
5. MANAGEMENT RESPONSIBILITY **5.1 Management commitment** Has top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by: a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and ensuring the availability of resources?	
5.2 Customer focus Has top management ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)?	

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5.3 Quality policy Has top management ensured that the quality policy: k) is appropriate to the purpose of the organization, l) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, m) provides a framework for establishing and reviewing quality objectives, n) is communicated and understood within the organization, and o) is reviewed for continuing suitability?	
5.4 Planning **5.4.1 Quality objectives** Has top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. Are the quality objectives measurable and consistent with the quality policy?	
5.4.2 Quality management system planning Has top management ensured that: p) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	

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5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Has top management ensured that the responsibilities and authorities are defined and communicated within the organization?	
5.5.2 Management representative Has top management appointed a member of the organization's management who, irrespective of other responsibilities, has responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization? **NOTE:** *The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.*	
5.5.3 Internal communication Has top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system?	

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5.6 Management review **5.6.1 General** Has top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? Has this review included assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives? Are records from management reviews maintained (see 4.2.4)?	
5.6.2 Review input Does input to management reviews include information on: a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) planned changes that could affect the quality management system, and recommendations for improvement?	
5.6.3 Review output Does output from management reviews include any decisions and actions related to: a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and resource needs?	

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6. RESOURCE MANAGEMENT **6.1 Provision of resources** Has the organization determined and provided the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.	
6.2 Human resources **6.2.1 General** Are personnel performing work affecting conformity to product requirements competent on the basis of appropriate education, training, skills and experience? **NOTE** *Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.*	

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6.2.2 Competence, training and awareness Does the organization: a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4)?	
6.3 Infrastructure Has the organization determined, provided and maintained the infrastructure needed to achieve conformity to product requirements? Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) process equipment, (both hardware and software), and c) supporting services (such as transport, communication or information systems).	

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6.4 Work environment Has the organization determined and managed the work environment needed to achieve conformity to product requirements? **NOTE.** *The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).*	
7. PRODUCT REALIZATION **7.1 Planning of product realization** Has the organization planned and developed the processes needed for product realization? Is this planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1)? In planning product realization, has the organization determined the following, as appropriate a) Quality objectives and requirements for the product b) The need to establish processes and documents, and to provide resources specific to the product c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance d) Records needed to provide evidence that the realization processes and resulting product fulfil requirements (see 4.2.4)? Is the output of this planning in a form suitable for the organization's method of operations?	

NOTE 1. *A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.* *NOTE 2:* **The organization may also apply the requirements given in 7.3 to the development of product realization processes.**	
7.2 Customer-related processes **7.2.1 Determination of requirements related to the product** Has the organization determined: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known and intended use, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization? **NOTE**. Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	

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7.2.2 Review of requirements related to the product Has the organization reviewed the requirements related to the product? Is this review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that: a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements? Are records of the results of this review and actions arising from this review maintained (see 4.2.4)? Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance? Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements? **NOTE:** In some situations, such as Internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.	

7.2.3 Customer communication Has the organization determined and implemented effective arrangements for communicating with customers in relation to: a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints?	
7.3 Design and development **7.3.1 Design and development planning** Has the organization planned and controlled the design and development of product? During the design and development planning, has the organization determined: a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development? Has the organization managed the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility? Is planning output updated, as appropriate, as the design and development progresses? **NOTE** Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.	

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7.3.2 Design and development inputs Are inputs relating to product requirements determined and records maintained (see 4.2.4)? Do they include: a) functional and performance requirements, d) applicable statutory and regulatory requirements, e) where applicable, information derived from previous similar designs, and f) other requirements essential for design and development? Are the inputs reviewed for adequacy to ensure the requirements are complete, unambiguous and not in conflict with each other?	
7.3.3 Design and development outputs Are the outputs of design and development in a form suitable for verification against the design and development input and approved prior to release? Do the design and development outputs: a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use? **NOTE** Information for production and service provision can include details for the preservation of product.	

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7.3.4 Design and development review At suitable stages, are systematic reviews of design and development conducted: a) to evaluate the ability of the results of design and development to fulfil requirements, and b) to identify any problems and propose necessary actions? Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed? Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)?	
7.3.5 Design and development verification Is verification performed to ensure that the design and development outputs have satisfied the design and development input requirements? Are records of the results of the verification and any necessary actions maintained (see 4.2.4)?	
7.3.6 Design and development validation Has design and development validation been performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application? Wherever practicable, is validation completed prior to the delivery or implementation of the product? Are records of the results of validation and any necessary actions maintained (see 4.2.4)?	

7.4 Purchasing **7.4.1 Purchasing process** Has the organization ensured that purchased product conforms to specified purchase requirements? Is the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product? Has the organization evaluated and selected suppliers based on their ability to supply product in accordance with the organization's requirements? Are the criteria for selection, evaluation and re-evaluation established? Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4)?	
7.4.2 Purchasing information Does purchasing information describe the product to be purchased, including where appropriate: a) Requirements for approval of product, procedures, processes and equipment, b) Requirements for qualification of personnel, and c) Quality management system requirements? Has the organization ensured the adequacy of specified purchase requirements prior to their communication to the supplier?	

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7.4.3 Verification of purchased product Has the organization established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements? Where the organization or its customer intends to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of product release in the purchasing information?	
7.5 Production and service provision **7.5.1 Control of production and service provision** Has the organization planned and carried out production and service provisions under controlled conditions? Do these controlled conditions include, as applicable: a) The availability of information that describes the characteristics of the product, b) The availability of work instructions, c) The use of suitable equipment, d) The availability and use of monitoring and measuring equipment, e) The implementation of monitoring and measurement, and f) The implementation of product release, delivery and post-delivery activities?	

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7.5.2 Validation of processes for production and service provision Has the organization validated any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence deficiencies become apparent only after the product is in use or the service has been delivered? Does validation demonstrate the ability of these processes to achieve planned results? Has the organization established arrangements for these processes including, as applicable: a) Defined criteria for review and approval of the processes, b) Approval of equipment and qualification of personnel, c) Use of specific methods and procedures, d) Requirements for records (see 4.2.4), and e) Revalidation?	

7.5.3 Identification and traceability Where appropriate, has the organization identified the product by suitable means throughout product realization? Has the organization identified the product status with respect to monitoring and measurement requirements throughout product realization? Where traceability is a requirement, has the organization controlled the unique identification of the product and maintained records (see 4.2.4)? **NOTE:** In some industry sectors, configuration management is a means by which identification and traceability are maintained.	
7.5.4 Customer property Has the organization exercised care with customer property while it is under the organization's control or being used by the organization? Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product? If any customer property is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer and maintain records (see 4.2.4)? **NOTE:** Customer property can include intellectual property and personal data.	

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7.5.5 Preservation of product Has the organization preserved the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements? As applicable does this preservation include identification, handling, packaging, storage and protection? Does this preservation also apply to the constituent parts of the product? Are records of the results of calibration and verification maintained (see 4.2.4)? When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed? Is this undertaken prior to initial use and reconfirmed as necessary? **NOTE** Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.	

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8. MEASUREMENT, ANALYSIS AND IMPROVEMENT **8.1 General** Has the organization planned and implemented the monitoring, measurement, analysis and improvement processes needed: a) To demonstrate conformity to product requirements b) To ensure conformity of the quality management system c) To continually improve the effectiveness of the quality management system? Does this include determination of applicable methods, including statistical techniques, and the extent of their use?	
8.2 Monitoring and measurement **8.2.1 Customer satisfaction** As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has fulfilled customer requirements? Are the methods for obtaining and using this information determined? **NOTE** Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.	

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8.2.2 Internal audit Has the organization conducted internal audits at planned intervals to determine whether the quality management system a) Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization b) Is effectively implemented and maintained? Has an audit programme been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? Are the audit criteria, scope, frequency and methods defined? Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process? Do auditors audit their own work? Has a documented procedure been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results? Has the management responsible for the area being audited ensured that actions are taken without undue delay to eliminate detected non-conformities and their causes?	

Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2)? **NOTE:** See ISO 19011 for guidance.	